

REMARKS

Claims 36-52 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting. This rejection is respectfully traversed.

Applicants respectfully submit that the present claims, which are limited to chimeric proliferating cells containing human DNA and bovine mitochondrial DNA, are directed to a patentably distinct species from the genus claimed in the '468 application which instead encompasses cross species nuclear transfer of a human cell or DNA into any enucleated animal oocyte. Withdrawal of the double patenting rejection is therefore respectfully requested.

Claims 36-52 stand rejected under 35 USC § 112 first paragraph as being non-enabled. This rejection is respectfully traversed.

The present specification provides irrefutable evidence that cross-species nuclear transfer of a human cell with an enucleated bovine oocyte yielded a NT unit, which in turn proliferated (divided by cell division) to yield multiple proliferating (dividing) cells. This is evidenced by the fact that the disclosed NT yielded an embryonic unit with multiple cells.

The Examiner disputes the validity of the claims on the basis that nuclear transfer may yield embryos containing both paternal and maternal mitochondrial DNA. This is noted, and is not disputed. However, the claims under examination merely require that the resultant proliferating cells contain human nuclear DNA and maternal (bovine) mitochondrial DNA. There is no requirement that human mitochondrial DNA be absent from the resultant chimeric human/bovine cells.

It is also noted that the Examiner indicates that the cybrid may not develop past the blastocyst stage. This also is not disputed. It is incontrovertible that not all X-species NT embryos will differentiate past the blastocyst stage. This also is not a requirement of the claims.

However, notwithstanding this fact, such cells have numerous disclosed substantial utilities, namely they can be used as donor cells for nuclear transfer, for transplantation studies (assays that assess immune reactivity against xenogenic mitochondrial antigens), these cells may be used to assay which particular cell surface antigens are expressed at the blastocyst stage, and these cells may be used in assays to assess how different growth factors and hormones affect differentiation and the expression of embryonic antigens.

The Examiner also disputes the predictability of obtaining proliferating cells as claimed. This is disputed, the specification teaches that the disclosed NT process yields NT embryos which divide (proliferate) to produce a plurality of proliferating (dividing) cells. (See the attached dictionary definition of “proliferate” from Merriam-Webster, YOURDICTIONARY.COM, AND OneLookDictionary Search). Also, in contrast to the rejection, it is predictable that cross-species nuclear transfer can be used to generate chimeric proliferating cells as claimed. In fact, X-species nuclear transfer has been used successfully to clone two animals, the Gwar and the Mouflon. (See attachments to Applicant’s reply which relate to cloning of these species by cross-species nuclear transfer)

The Office Action further suggests that the phenotype of the cells is not provided. This is disputed, the disclosure clearly indicates that the produced

cells which result from the recited cross-species nuclear transfer an embryonic cells.

Also, the comment that the specification does not define which is the "inner portion" of the NT unite is clearly indefensible. In fact, blastocyst stage embryos have a characteristic morphology and the inner portion is very discernible. (See the figure filed with the application in this regard).

Based on the foregoing, one skilled in the art would be able to recently discern and isolate the resultant chimeric proliferating cells from the inner-most portion of the NT embryo and use them as disclosed in the subject application.

Withdrawal of the enablement rejection of claims 36-52 is respectfully requested.

Claims 36-52 stand rejected as being vague and indefinite in the recitation "inner portion" of the NT unit. This rejection is not defensible. As noted above, and as substantiated by the figures, one skilled in the art can readily and easily discern the "inner portion" of an NT unit. Indeed, this is routine to the skilled artisan.

Withdrawal of the § 112 second paragraph rejection of claims 36-52 is respectfully requested.

Claims 48, 49, 50 and 52 stand rejected under 35 USC § 102(b). This rejection is vigorously traversed.

Heynecker relates to the production of transgenic bovine embryos that contain and express a human transgene. The reference does not teach or suggest the claimed chimeric cells containing the nuclear DNA of a human cell and bovine mitochondrial DNA. It is an unreasonable interpretation of the claim to

suggest that transgenic bovine cells would read on the claims if they are properly construed based on the teaching of the application. Indeed, the claims provide that the cells result from transplantation of a human cell or human cell nuclear into an oocyte.

Clearly, based on the means they are produced this would not need an transgenic bovine cells containing a human gene as alleged in the Office Action.

Based on the foregoing, withdrawal of the § 102(b) rejection of claims 48, 49, 50 and 52 is respectfully requested.

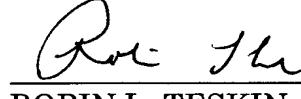
It is believed that these remarks should place this case in condition for allowance. A Notice to that effect is respectfully solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #100375.54383US).

Respectfully submitted,

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